

ABSTRACT

This invention provides a process of sterilizing a medical device, and preferably the
5 contents of a sealed container which comprises said medical device, comprising the step of
exposing said medical device to ultraviolet radiation whereby the D_{value} of Bacillus
stearothermophilus (ATCC 7953) is at least 3.9 mJ/cm² ultraviolet radiation in the range of
240-280 nm to the spore. Further, this invention provides a process of sterilizing a medical
device comprising the step of subjecting said medical device to ultraviolet radiation wherein
10 the minimum total energy density of said ultraviolet radiation in the range of 240-280 nm
which reaches the microorganisms present on said medical device is at least 18 mJ/cm².

This invention further provides an apparatus for delivering UV radiation to a medical
device for sterilization comprising a radiation source and a reflector for said radiation source
wherein said reflector directs radiation from said radiation source such that at least 3 J/cm²
15 broad spectrum radiation of which at least 50 mJ/cm² of said radiation is UV radiation in the
range of 240-280 nm to a treatment area for said medical device, said treatment area is at the
focal plane of said reflector. This invention provides a process and apparatus in which
sterilization can be achieved in less than 20 seconds, preferably less than 15 seconds, more
preferably in less than 5 seconds. The process and apparatus are efficient and continuous.